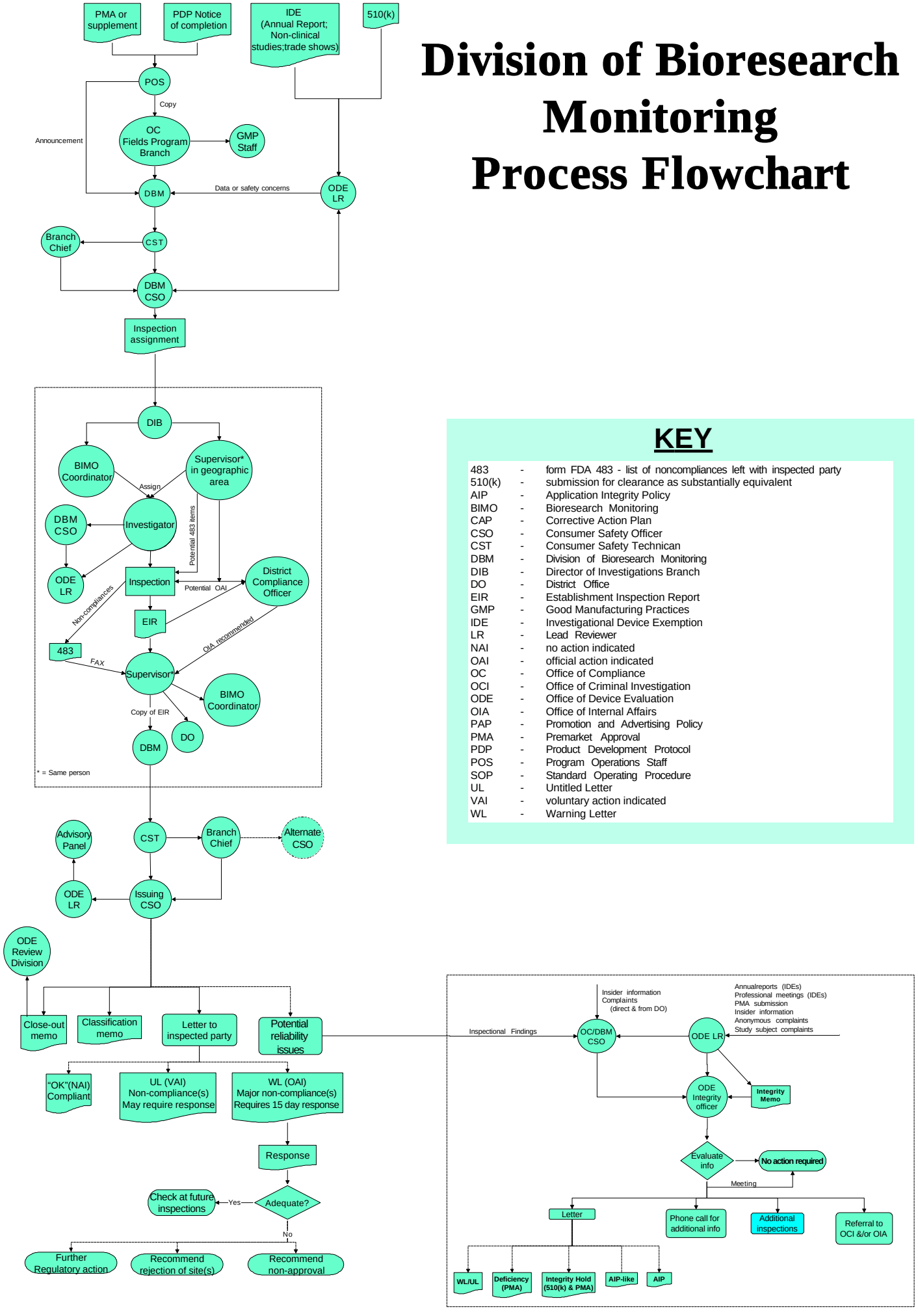
Division of Bioresearch Monitoring Process Flowchart



KEY

483	-	form FDA 483 - list of noncompliances left with inspected party
510(k)	-	submission for clearance as substantially equivalent
AIP	-	Application Integrity Policy
BIMO	-	Bioresearch Monitoring
CAP	-	Corrective Action Plan
CSO	-	Consumer Safety Officer
CST	-	Consumer Safety Technican
DBM	-	Division of Bioresearch Monitoring
DIB	-	Director of Investigations Branch
DO	-	District Office
EIR	-	Establishment Inspection Report
GMP	-	Good Manufacturing Practices
IDE	-	Investigational Device Exemption
LR	-	Lead Reviewer
NAI	-	no action indicated
OAI	-	official action indicated
OC	-	Office of Compliance
OCI	-	Office of Criminal Investigation
ODE	-	Office of Device Evaluation
OIA	-	Office of Internal Affairs
PAP	-	Promotion and Advertising Policy
PMA	-	Premarket Approval
PDP	-	Product Development Protocol
POS	-	Program Operations Staff
SOP	-	Standard Operating Procedure
UL	-	Untitled Letter
VAI	-	voluntary action indicated
WL	-	Warning Letter